Amendments to the Claims

Please cancel claims 20, 22-30, 33-40, 44-51 and 54-56 without prejudice or disclaimer to applicants' rights to pursue the subject matter of these claims in this or a related application.

Please amend claims 5, 7, 8, 11, 19, 21, 31, 42 and 53 under the provisions of 37 C.F.R. §1.121, as set forth in the Federal Register on June 30, 2003 as follows:

1. (Original) A pharmaceutical composition comprising

an aqueous carrier;

from 0.1 mg/ml to 20 mg/ml of the composition of a pharmaceutically acceptable salt of a peptide having the structural formula

NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

a substituted β-cyclodextrin in an amount effective to dissolve the peptide in the aqueous carrier,

wherein the composition has a pH between 4 and 9.

2. (Original) The pharmaceutical composition of claim 1, wherein the concentration of the salt of the peptide is at least 0.5 mg/ml.

3. (Original) The pharmaceutical composition of claim 2, wherein the concentration of the salt of the peptide is from 0.5 mg/ml to 10 mg/ml.

4. (Original) The pharmaceutical composition of claim 3, wherein the concentration of the salt of the peptide is from 0.5 mg/ml to 2.5 mg/ml.

5. (Currently Amended) The pharmaceutical composition of ~~any one of claims 1-4,~~ claim 1 wherein the composition has a pH between 6.5 and 8.5.

6. (Original) The pharmaceutical composition of claim 5, wherein the composition has a pH between 7.5 and 8.5.

7. (Currently Amended) The pharmaceutical composition ~~of any~~

~~one of claims 1-6,~~ claim 1 wherein the pharmaceutically acceptable salt is an acetate salt.

8. (Currently Amended) The pharmaceutical composition of ~~any one of claims 1-7,~~ claim 1 wherein the substituted β-cyclodextrin is a hydroxypropyl, a sulfobutyl ether, or a sulfopropyl ether substituted β-cyclodextrin.

9. (Original) The pharmaceutical composition of claim 8, wherein the substituted β-cyclodextrin is a sulfobutyl ether substituted β-cyclodextrin.

10. (Original) The pharmaceutical composition of claim 7, wherein the substituted β-cyclodextrin is hepta-(sulfobutyl ether)-β-cyclodextrin.

11. (Currently Amended) The pharmaceutical composition of ~~any one of claims 1-10,~~ claim 1 further comprising a pharmaceutically acceptable buffer in an amount and of a type suitable to make the pH of the pharmaceutical composition in the range of 4-9.

12. (Original) A pharmaceutical composition comprising

an aqueous carrier;

from 0.1 mg/ml to 20 mg/ml of the composition of an acetate salt of a peptide having the structural formula NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

from 70 mg/ml to 170 mg/ml of the composition of hepta-(sulfobutyl ether)-β-cyclodextrin,

wherein the peptide and the hepta-(sulfobutyl ether)-β-cyclodextrin are dissolved in the aqueous carrier; and

wherein the composition has a pH between 6.5 and 8.5.

13. (Original) The pharmaceutical composition of claim 12, wherein the concentration of the acetate salt of the peptide is at least 0.5 mg/ml.

14. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 mg/ml to 10 mg/ml.

15. (Original) The pharmaceutical composition of claim 13, wherein the concentration of the acetate salt of the peptide is from 0.5 to 2.5 mg/ml.

16. (Original) The pharmaceutical composition of claim 13, wherein the concentration of hepta-(sulfobutyl ether)-β-cyclodextrin is 120 mg/ml, and wherein the pH of the composition is between 7.5 and 8.5.

17. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 1.0 mg/ml.

18. (Original) The pharmaceutical composition of claim 16, wherein the concentration of the acetate salt of the peptide is 2.5 mg/ml.

19. (Currently Amended) A method of alleviating symptoms of systemic lupus erythematosus (SLE) in a human subject comprising administering to the human subject the pharmaceutical composition of ~~any one of claims 1-18~~ claim 1 in an amount effective to alleviate the symptoms

of SLE in the human subject.

20. (Canceled)

21. (Currently Amended) A process for manufacturing the pharmaceutical composition of ~~any one of claims 1-18~~ claim 1 comprising the steps of:

a) preparing a solution of a substituted β-cyclodextrin in an aqueous carrier at a predetermined concentration;
b) adding a predetermined amount of a pharmaceutically acceptable salt of the peptide NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1) to the solution of step a);
c) adjusting the pH of the solution of step b) until the peptide dissolves in the solution; and
d) if necessary, adjusting the pH of the solution of step c) to a pH of 4-9, thereby manufacturing the pharmaceutical composition.

Claims 22-30. (Canceled)

31. (Currently Amended) A pharmaceutical composition prepared by the process of ~~any one of claims 21-30~~ claim 21.

32. (Original) A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:

a) lowering the temperature of the pharmaceutical composition to -40°C;
b) holding the temperature at -40°C for a predetermined time;

c) raising the temperature of the solution to 20°C;

d) holding the temperature at 20°C for a predetermined time; and

e) reducing the pressure and holding the temperature at 20°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

Claims 33-40. (Canceled)

41. (Original) The process of claim 32, wherein

step a) is performed within 2 hours;

step b) is performed within 3 hours;

step c) is performed over 13 hours and at a pressure of 110μbar;

step d) is performed over 13 hours and at a pressure of 110μbar; and

step e) is performed over 5 hours and the pressure is reduced to 10μbar.

42. (Currently Amended) A lyophilized pharmaceutical composition prepared by the process of ~~any one of claims 32-41~~ claim 32.

43. (Original) A process of lyophilizing the pharmaceutical composition of claim 2, comprising the steps of:

a) lowering the temperature of the pharmaceutical composition to -45°C;

b) holding the temperature at -45°C for a predetermined time;

c) raising the temperature of the solution to -20°C;

d) raising the temperature of the solution to 25°C; and

e) holding the temperature at 25°C for a predetermined time, thereby lyophilizing the pharmaceutical composition.

Claims 44-51. (Canceled)

52. (Original) The process of claim 43, wherein

step a) is performed within 6 hours;

step b) is performed within 3 hours;

step c) is performed over 19 hours and at a pressure of 150μbar;

step d) is performed over 13 hours and at a pressure of 150μbar; and

step e) is performed over 8 hours and at a pressure of 150μbar.

53. (Currently Amended) A lyophilized pharmaceutical composition prepared by the process of ~~any one of claims 43-52~~ claim 43.

Claims 54-56. (Canceled)

57. (Original) A lyophilized pharmaceutical composition comprising

a pharmaceutically acceptable salt of a peptide having the structural formula

NH_2-Gly Tyr Tyr Trp Ser Trp Ile Arg Gln Pro Pro Gly Lys Gly Glu Glu Trp Ile Gly-COOH (SEQ ID NO:1); and

a substituted β-cyclodextrin.

58. (Original) A packaged pharmaceutical composition comprised of:

a packaging material; and

a predetermined amount of the lyophilized pharmaceutical composition of claim 57.